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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,101	03/30/2001	Jason Pluta	DEX-0205	4789

26259 7590 02/11/2002

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EXAMINER

DAVIS, NATALIE A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 02/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/823,101

Applicant(s)

PLUTA ET AL.

Examiner

Natalie A. Davis

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 7-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Applicant's election with traverse of Group I, claims 1-6 and 19 and species SEQ ID NO: 2 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the inventions are not independent or distinct, as a proper search of Group I should reveal art relating to Groups II-XI and searching 13 sequences would not be an undue burden. This is not found persuasive because an independent search of each sequence, a fragment thereof and variations thereof does pose an undue burden and Groups I-XI are distinct inventions as indicated in the previous office action. The requirement is still deemed proper and is therefore made FINAL.

The previous office action indicates Group I as consisting of claims 1-6 and 19. This is in error, as Group I consists of claims 1-6 and 9. Accordingly, claims 1-6 and 9 are being examined as belonging to the elected Group I, while claims 7-8 and 10-25 are withdrawn from examination as being drawn to a non-elected invention.

### ***Information Disclosure Statement***

The information disclosure statement filed 24 November 2001 has been considered. A signed copy is attached hereto.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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2. Claims 1-6 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising SEQ ID NO: 2, does not reasonably provide enablement for an polynucleotide fragment of SEQ ID NO: 2, wherein the fragment is at least 15 contiguous nucleobases long.

3. The specification discloses the polynucleotides of the invention as Stomach Cancer Specific Genes or SSGs, which are believed to be useful in assays for detecting, staging, monitoring, prognosticating, imaging and treating cancers (p. 1). Polynucleotides are disclosed as nucleic acid sequences comprising single- and double-stranded DNA, that is a mixture of single- and double-stranded regions, single- and double-stranded RNA or hybrids thereof, and fragments containing 15 contiguous nucleobases of SEQ ID NO: 2.

4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. There are many nucleic acid molecules that may or may not perform the same biological functions and the specification does not give any guidance to which molecules having at least 15 contiguous nucleobases to SEQ ID NO: 2 will exhibit the biological activities as the claimed, or any guidance as to which regions of the sequence must be preserved so the molecule will function as claimed. Thus, it would be an undue burden to one of ordinary skill in the art to assay for claimed sequences, which are capable of functioning as contemplated. One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to any polynucleotide fragment that comprises at least 15 contiguous nucleobases of SEQ ID NO: 2, and a complement thereof and applicant has not enabled all of these types of modifications because it has not been shown that these polypeptides are capable of functioning as that which is being disclosed. Furthermore, there is no guidance in the specification of how to make and select for fragments of SEQ ID NO: 2, which will function as contemplated. Accordingly, one of ordinary skill in the art would not know how to make or use the invention as claimed.

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5. Claims 1-2 are drawn to a polynucleotide, which comprises variations, a nucleic acid sequence, which hybridizes to an antisense sequence of SEQ ID NO: 2 and an antisense oligonucleotide, which hybridizes to a polynucleotide of claim 1.

6. Lehninger, et al. (Principles of Biochemistry, 2<sup>nd</sup> Ed., Worth Publishers, NY, 1993) is cited in order to establish the general state of the art and the level of predictability of hybridization. Lehninger, et al. teach that hybridization requires the pairing of nucleotide bases of two nucleic acid strands which are complementary (p. 343) and teaches that complementary strands are not identical in either base pair sequence or composition, that is wherever adenine appears in one chain, thymidine is found in the other and wherever guanine appears in one chain, cytosine is found in the other (p. 335). Applicant has not taught how to hybridize identical nucleic acid strands or for example a degenerate strand of SEQ ID NO:2 to that of SEQ ID NO:2, one to the other. In addition, the specification does not disclose whether the polynucleotides sequences hybridize partially or completely or which regions of the strands are hybridizing. The specification defines polynucleotides as nucleic acid sequences comprising single- and double-stranded DNA, that is a mixture of single- and double-stranded regions, single- and double-stranded RNA or hybrids thereof, but does not provide any guidance as to how one would hybridize the various polynucleotides. In view of the Lehninger, et al. teaching, one of ordinary skill in the art would not clearly expect to be able to hybridize two identical nucleic acid strands one to the other or a degenerate strand of SEQ ID NO:2 to SEQ ID NO:2. In addition, there are many polynucleotides with degenerate coding sequences of SEQ ID NO:2, which encode the same protein and it would be an undue burden to one of ordinary skill in the art to assay for claimed sequences. One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to any antisense oligonucleotide, which hybridizes to a polynucleotide of claim 1, and any nucleic acid which hybridizes to an antisense of SEQ ID NO: 2 and applicant has not enabled all of these types of hybridizations because it has not been shown that these polynucleotides are capable of hybridizing. Therefore, in view of the lack of predictability of the prior art, the breadth of the claims and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as claimed.

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***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipate by Kato, et al., (1983).

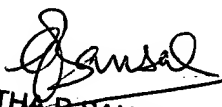
9. Kato, et al., disclose a genomic clone that contains the human gastrin gene, which was isolated from a human gene library. Since the specification does not indicate whether polynucleotides hybridize partially or completely, the sequence set forth by Kato, et al. anticipates claim 1 as it discloses a nucleic acid, which may partially hybridize to a fragment, variation and antisense sequence of SEQ ID NO: 2. Kato, et al. further set forth a vector, host cell, and a method of producing a polypeptide. It is inherent (claim 9) that the polynucleotide may be used to diagnose stomach cancer, since it was derived from the gastrin gene.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, Ph.D.  
January 28, 2002

  
GEETHA P. BANSAL  
PRIMARY EXAMINER